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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,708	09/19/2001	Gerald R. Crabtree	STAN201	4284

24353 7590 11/17/2005

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EXAMINER

MCGARRY, SEAN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 11/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/960,708

Applicant(s)

CRABTREE ET AL.

Examiner

Sean R. McGarry

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 12 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

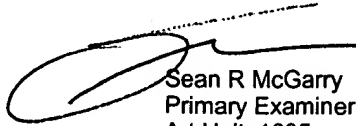
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.


Sean R. McGarry
Primary Examiner
Art Unit: 1635

Continuation of 11. does NOT place the application in condition for allowance because: of the reasons of record. Applicant continues to argue that the rejections of record are in error. Applicant continues to assert that the prior art fails to show that the administration of FK506 has any effect on existing papillomas. Applicant continues to point out that the authors of the prior art reference have not demonstrated that they appreciated the specific action of FK506 on papillomas. Applicant continues to assert, without any evidence, that "it is entirely possible and in no way inconsistent with the teachings of Jiang et al, that FK506 has no effect on TPA-induced papillomas." Applicants' statement may not be inconsistent with the prior art teachings, but would certainly be inconsistent with applicants own disclosure and claims. Applicant claims treating tumors, of which papillomas are included, with FK506 (see claim 40, for example). Applicants own specification has shown the activity of FK506. The mice of Jiang et al have tumors that were indeed existing at the time of FK506 administration. Applicant has provided no evidence that FK506 would, for some reason, function differently for Jiang et al than as demonstrated in their own specification. The fact is that FK 506 functions as an angiogenesis/vascular development inhibitor. Jiang et al treated mice that have papillomas with FK506 regardless of how the tumors were induced (Applicant invention does not appear to be limited to a specified class of tumors such that FK506 would function in that class as opposed to a separate class that, if a tumor was induced by some specified means would preclude FK506 from functioning as demonstrated in the instant specification.) There simply is no reason to question that FK506 functions as the instant specification has demonstrated it to function. The prior art does not have to appreciate the function taught in the instant application. The disclosure of the prior art is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function. A prima facie case of inherency has been made and the burden has been properly shifted to applicant to disprove the assertion of inherency. Applicant would need to demonstrate, for example that FK506 administered to mice with TPA induced papillomas does not function to inhibit angiogenesis as has been shown to be the "questioned function" of FK506 by the instant specification. It is noted that such evidence would not be considered at this point of prosecution since the burden was properly shifted to applicant, at the very latest, in the non-final action mailed 11/26/04. Applicant asserts that the examiner offers that it is only a possibility that FK506 acts to inhibit tumor growth or angiogenesis. However, it clearly would flow that FK506 would function as demonstrated in the instant application even if not appreciated by the prior art reference. Applicant is directed to claim 15 where the claims do not even require that tumor growth inhibition be due to inhibition of angiogenesis. Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.